UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/985,007	12/04/97	MIURA	2558/KIP N/C

HM12/0122

SHAHAN ISLAM FRIEDMAN SIEGELBAUM
SEVEN BECKER FARM ROAD
ROSELAND NJ 07068-1757

CHIN, C EXAMINER

ART UNIT | PAPER NUMBER

01/22/99

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/30/98.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) 13 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-13 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

PTOL-326 (Rev. 10/95)

* U.S GPO: 1996-409-290/40029

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I - claims 1-12 in Paper No. 6 is acknowledged.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 U.S.C. § 112

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 are vague and indefinite. The recitation of "i.e. an antigen as an object to be measured" in line 4 is not clear as to whether the example is intended to be exemplary or limiting. If the "medical substance" is an antigen, then a specific binding reagent such as an antibody specific for the antigen would be required on the resonance material to provide for detection of the antigen. The claim is also confusing with respect to "detecting a condition for generating" the resonance phenomenon. The resonance phenomenon is typically generated by

totally internally reflected light and the resulting evanescent wave at the interface between two materials, such as glass and gold in a surface plasmon resonance sensor. In a surface plasmon resonance sensor, it is a change in the surface plasmon resonance signal upon the presence of analyte that is detected. Thus, a sensor is not detecting a condition for generating the resonance phenomenon because the presence or absence of analyte would not effect the totally internally reflected light.

Claims 2 and 6 are vague and confusing for same reasons set forth above with respect to the recitation of "said condition for generating said resonance phenomenon is changed when a mixture of antibody...". The presence of antibody and sample will not effect the generation of the resonance phenomenon.

Claims 3 and 7 are confusing because claims 2 and 6, respectively, define the medical substance as being fixed to the sensor while claims 3 and 7 refine the medical substance as being in the sample. The claim is also vague and confusing for the reasons set forth above with respect to the recitation of "a change of said condition for generating said resonance phenomenon...".

Claims 4 and 8 are vague and indefinite. The recitation of "i.e. an antigen as an object to be measured" in line 4 is not clear as to whether the example is intended to be exemplary or limiting.

Claim 9 is vague and indefinite. The recitation of "i.e. an antigen as an object to be measured" in line 8 is not clear as to whether the example is intended to be exemplary or limiting.

Claims 10 and 11 are vague and confusing for the same reasons set forth above with respect to claims 1 and 5 in reciting that the condition for generating the surface plasmon resonance phenomenon is changed in the presence of sample and reagents.

Claim 12 is vague and indefinite. The recitation of "i.e. an antigen as an object to be measured" in line 4 is not clear as to whether the example is intended to be exemplary or limiting.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Batchelder et al.

Batchelder et al (U.S. Patent 4,844,613) disclose an optical sensor that uses surface plasmon resonance to detect the presence of a specific material. The sensor comprise a prism (11), a transparent body (12), which is coated with a thin gold film (14), and a layer of antibody on the thin film of gold. A photodiode array (16) is provided to detect a signal from the sensor.

6. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlan et al.

Finlan et al (U.S. Patent 4,997,278) disclose a sensor that uses surface plasmon resonance to monitor the reaction between a sample and an antibody layer on the sensor. The antibody layer is on a metallic film that is formed on the surface of an optically transmissive component in the form of a hemicylindrical lens and slide.

7. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlan et al.

Finlan et al (U.S. Patent 5,047,213) disclose a biological sensor which utilizes the phenomenon of surface plasmon resonance to detect the refractive index change occurs when two components, such as an antigen and antibody, react with one another. Surface plasmon resonance takes place at the sloping exit surface of an optical waveguide (23). The input end (12) of the optical waveguide is connected to a light source. A layer (25) of metal is applied to the sloping exit surface to cause total internal reflection of the light proceeding down the optical waveguide. Reflected light is detected by detector (13). A sensitive layer of antibody (26) is applied to the metal layer. Sample reacts with the layer of antibody in such a way that the refractive index changes. Provided conditions are correct, this variation in refractive index can be monitored in detector (13) by virtue of the surface plasmon resonance which occurs in the area of total internal reflection.

8. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Shanks et al.

Shanks et al (U.S. Patent 4,810,658) discloses a sensor for performing optical immunoassays. The sensor comprises a light source, a waveguide that supports a layer of specific binding material, and one or more photodetectors to detect a signal(s) from the waveguide that indicates the presence or amount of a desired analyte.

9. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart.

Stewart (U.S. Patent 4,857,273) discloses a biosensor comprising an optically dense body with a coating sensitized to a specific assay species and an input and output coupling structure. Light signal response is enhanced by incorporating a partially reflecting, partially transmitting medium between the coupling structure and optically dense body having lower refractive index. The thickness of such medium is chosen so that light may be coupled frustrated total internal reflection and to enable the medium to serve as a resonant mirror.

10. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cush et al.

Cush et al (Biosensors & Bioelectronics 8 (1993), 347-353) discloses a sensor for performing optical immunoassays using surface plasmon resonance (see Figure 1).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can

normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
January 16, 1999

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641